K003522

FEB 1 3 2001

ONUX
MEDICAL, INC

510(k) Summary

11/10/2000

Onux Medical, Inc.. Contact Person:	Gregory E. Sancoff
Trade or Proprietary Name:	Salute
Common or Usual Name:	Endoscopic stapler and staple
Classification Name:	Endoscopic and/or Accessory, Implantable Staple

Devices to Which Equivalence is Claimed
The subject device has equivalency to the Touche device by Onux Medical, Inc. (formerly Mill Pond, Inc.) and the Endo Hernia Stapler and the Tacker, both from U.S. Surgical Corp.

Description of Subject Device
The subject device is a manual stapling instrument for endoscopic and open surgical procedures. It consists of a reusable handpiece and shaft, and a single-use disposable that contains the wire from which the staples are formed. The shaft is also available in a disposable version. The staple material is made from widely accepted implant-grade metals.

Intended Use of Subject Device
Both the subject device and the Endo Hernia Stapler and the Tacker are indicated for fixation of prosthetic mesh material and approximation of tissue in endoscopic and open surgical procedures. The devices have similar contraindications.

Comparison of Technical Aspects
The subject device and the Touche device are technologically the same except the subject device uses a manual lever rather than an electric motor for the energy source and they form different wire constructs at the end of their shafts. The subject device and both the Endo Hernia Stapler and the Tacker deploy metal constructs into tissue from the tip of a shaft. Animal tests performed with the subject device and the Endo Hernia Stapler showed that the subject device had equivalent performance characteristics compared to the Endo Hernia Stapler.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2001

Mr. Gregory E. Sancoff
Pesident and CEO
Onux Medical, Inc.
5 Merrill Drive
Hampton, New Hampshire 03842

Re: K003522
Trade Name: Salute™ Stapler and Staples
Regulatory Class: II
Product Code: GDW
Dated: November 10, 2000
Received: November15, 2000

Dear Mr. Sancoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003522

Statement of Indications for Use

INDICATIONS

The Salute™ Stapler and Staples have applications in a variety of endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

Prescription Use ✓
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003522